

K963454

(914) 963-2040

(800) 431-2972

FAX (914) 963-2567

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**TAB F: 510(k) Summary of Safety and Effectiveness**

Name, address, phone and fax numbers for person submitting the 510(k) notification:

Arnold Silverman, President  
Skil-Care Corporation  
167 Saw Mill River Road  
Yonkers, NY 10701  
Phone: 1-914-963-2040  
Fax: 1-914-963-2567

Contact person: Arnold Silverman

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Device name:

<u>Trade name:</u>	Cushion Belt, Adjusta-Loop Cushion Belt Quick-Release Cushion Belt, Cushion Slider Belt
<u>Common name:</u>	Same
<u>Classification name:</u>	Wheelchair Accessory

Predicate device:

Cushion Belt, Adjusta-Loop Cushion Belt, Quick-Release Cushion Belt and Cushion Slider Belt marketed by Skil-Care Corporation.

Device Description:

*Cushion Belt:* A 26-inch-long, 6 1/2-inch wide cushion comprised of polyester on the outside and 3/4-inch-thick polyurethane foam inside. It has 1 1/2-inch-wide webbing and webbing loops sewn to each end. Webbing is polyester. Edges are finished with a bias cut binding. Webbing criss-crosses behind patient and secures to wheelchair or bed. Device is made in one size.

*Cushion Slider Belt:* Identical to above with the addition of a crotch pad sewn to the bottom center front. The pad is lined with 1/4-inch-thick polyurethane foam and has a 1 1/8-inch-wide strap sewn on that is either placed directly under the patient or under the wheelchair seat and secured to the cross brace under the wheelchair to prevent he patient from sliding down. This device is designed for wheelchair use only.

***Adjusta-Loop Cushion Belt:*** Identical to the Cushion Belt except that the webbing is fitted with slider buckles that permit it to form adjustable loops that slip over the wheelchair kickspurs. The product is used by care givers who do not want to tie the webbing ends to the wheelchair. The device is intended for wheelchair use only.

***Quick Release Cushion Belt:*** Identical to the Cushion belt except that one section of webbing is terminated with a "male" Delrin buckle component and the other end with a "female" Delrin buckle component. The buckle secures behind the wheelchair backrest.

**Indications for use:**

The Cushion Belt is intended for patients who require a safety belt when in the wheelchair or bed. It is also used as a reminder not to leave the wheelchair or bed without assistance.

The Cushion Slider Belt is intended for patients who require a safety belt while in the wheelchair and who also need added control to prevent sliding down in the wheelchair.

The Adjusta-Loop Cushion Belt is intended for patients who require a safety belt while in the wheelchair and who require a reminder not to leave the wheelchair without assistance.

The Quick-Release Cushion Belt is intended for patients who require a safety belt while in the wheelchair and who require a reminder not to leave the wheelchair without assistance.

**Comparative information:**

The device (devices) used for comparative purposes is (are) currently marketed as described in this submission. Device (devices) is (are): Cushion Belt, Cushion Slider Belt, Adjusta-Loop Cushion Belt, Quick-Release Cushion Belt.

These devices are currently exempt from 510(k) Premarket Notification Procedures and Good Manufacturing Practice Regulations and are legally marketed by Skil-Care Corporation as of the date of this submission. Skil-Care Corporation has been marketing and commercially distributing these devices for approximately 18 years.

The difference from our currently marketed devices are that the labeling will be changed to incorporate many of the suggestions in FDA's draft document, "Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints.

The use of all patient restraints in nursing homes are subject to Health Care Financing Administration's Regulations which prohibit the use of any restraint, physical or chemical, imposed for the purpose of discipline or convenience. Further, most health care facilities are accredited. HCFA rules governing appropriate use and accreditation standards for device use and personnel training provide the control necessary to ensure that the devices are used correctly. The application of these standards along with public awareness and health care provider training have contributed significantly to ensuring that the least restrictive restraint is used, that restraints are used only when needed for proper medical treatment, and that their use is under appropriate supervision.